In the United States Court of Federal Claims

No. 17-1418V Filed: July 3, 2019 Reissued for Publication: July 18, 2019¹

KEITH NOE and CAROL LANGLEY, o/b/o J.J.N., a minor,

Petitioners,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

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Vaccine Act; DTaP and MMR Vaccinations; Table Claim; Non-Table Claim; Acute Encephalopathy; Autism.

Keith Noe and Carol Langley, pro se, Brockton, MA.

Lara A. Englund, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent. With her were **Heather L. Pearlman**, Assistant Director, Torts Branch, Civil Division, **Catharine E. Reeves**, Deputy Director, Torts Branch, Civil Division, **C. Salvatore D'Alessio**, Acting Director, Torts Branch, Civil Division, and **Joseph H. Hunt**, Assistant Attorney General, Civil Division.

OPINION

HORN, J.

On October 3, 2017, <u>pro</u> <u>se</u> petitioners Keith Noe and Carol Langley, parents of, and on behalf of, minor J.J.N., filed a petition for compensation in the above-captioned

¹ This Opinion was issued under seal on July 3, 2019. The parties did not propose any redactions to the July 3, 2019 Opinion, and the court, therefore, issues the Opinion without redactions for public distribution.

² Petitioners filed a motion to redact in which they "request that all confidential and personal information regarding our son [J.J.N.] and daughter LSN be redacted from being posted or released publicly." In recognition of J.J.N.'s status as a minor, this court refers to him as "J.J.N." The court notes that even though petitioners requested the redactions, there are references to J.J.N. by his real name in petitioners' filings. In this Opinion, the court has changed those quotations out of respect for J.J.N.'s minor status.

case, pursuant to the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. §§ 300aa-1-34 (2012), asking for relief based on alleged injuries suffered by J.J.N. Petitioners allege these injuries occurred because of vaccinations J.J.N. received on September 24, 2014 and November 25, 2014. Petitioners subsequently filed an amended petition on February 14, 2018. The case was originally assigned to Special Master Thomas L. Gowen, but was transferred to Special Master Brian H. Corcoran of the United States Court of Federal Claims on May 30, 2018.3 On February 4, 2019, Special Master Corcoran denied petitioners' request for compensation, finding that petitioners had presented insufficient evidence to prove their claims. See K.N. v. Sec'y of Health & Human Servs., No. 17-1418V, 2019 WL 1123016, at *2 (Fed. Cl. Spec. Mstr. Feb. 4, 2019). On February 13, 2019, the pro se petitioners submitted a document titled "Notice of Appeal," which, as discussed further below, the court treats as a timely motion for review of Special Master Corcoran's decision. On March 7, 2019, petitioners filed a memorandum of objection with this court, but also tried to add additional exhibits to the record in support of their motion for review of the Special Master's decision denying petitioners' claim, which had not been filed with the Special Master before he issued his February 4, 2019 decision.4

FINDINGS OF FACT

According to the records before the court, J.J.N. was born on June 19, 2013 at 39 weeks. In the petition for compensation, petitioners alleged that prior to the vaccinations at issue in this case, J.J.N. was a "very active, happy, easy baby." Petitioners requested at J.J.N.'s two-month physical examination on August 20, 2013 that J.J.N.'s vaccines be staggered. At his nine-month well-baby exam on February 27, 2014, it was reported by petitioners that J.J.N. occasionally had "hand flapping," although the examiner stated in the medical report it seemed as if J.J.N. was just "hitting his thighs." Special Master Corcoran found that this hand flapping was possibly one of "some vague preliminary signs" of developmental problems, see K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *2, but petitioners maintain the "hand flapping" was normal, or was at least thought to be normal according to the care provider petitioners consulted on February 27, 2014.

At a sick visit on July 5, 2014, it was noted in the medical record that J.J.N. had a rash the petitioners felt might be eczema. On September 24, 2014, J.J.N. received his one-year, well-baby check-up at fifteen months of age and was given the first round of vaccines, which included the inactivated polio virus, the pneumococcal conjugate, haemophilus influenzae, and influenza vaccines. A vaccine "catch up" occurred at the September 24, 2014 check-up because of J.J.N. being five months behind on

³ The Chief Special Master may reassign a case as necessary for the "efficient administration of justice." Vaccine Rule 3(d) (2019).

⁴ According to Vaccine Rule 23(a), "[t]o obtain review of the special master's decision, a party must file a motion for review with the clerk [of the United States Court of Federal Claims] within 30 days after the date the decision is filed." <u>See</u> Vaccine Rule 23(a) (2019).

vaccinations. This vaccine "catch up" consisted of the inactivated polio virus, the pneumococcal conjugate, haemophilus influenzae, and influenza vaccines. On October 1, 2014, J.J.N.'s primary care physician saw him for an insect bite that petitioners contend may have occurred on September 28, 2014. Other than removing a tick from his shoulder blade the medical record noted that J.J.N. was "normal" in all aspects, including temperament. Special Master Corcoran noted in his dismissal of petitioners' case that at various sick visits that occurred on October 1, October 3, and November 3, 2014, J.J.N.'s primary care provider included "no report of a reaction independent from the primary reasons for seeking treatment," at any of these visits. See id.

On November 5, 2014, petitioners reported to their primary care physician that J.J.N. was not sleeping or making eye contact, and was "extremely fussy, and irritable." Petitioners expressed concern at the November 5, 2014 check up about "underlying 'serious illness' including Lyme, as well as concerns about autism and developmental delay or regression." According to the medical record, on November 5, 2014, J.J.N.'s blood test was negative for Lyme disease.

On November 13, 2014, J.J.N. had a pediatric visit at which it was brought up by petitioners that J.J.N. may have been experiencing seizures and other developmental difficulties such as "walking high up on his tip toes" and "eye flickering." At J.J.N.'s 18-month well baby exam, on November 25, 2014, J.J.N. received the second round of vaccines, which consisted of measles-mumps-rubella (MMR), varicella, diphtheriatetanus-acellular pertussis (DTaP) and another flu vaccine. At this same exam, on November 25, 2014, petitioners repeated their concerns about J.J.N.'s seizures and developmental difficulties such as "walking high up on his tip toes" and "eye flickering." The medical record before this court indicates that the pediatrician at this check-up, however, noted J.J.N. as having a "normal" temperament and being "alert" and "very active."

On December 11, 2014, J.J.N. was referred by his pediatrician, Dr. Wilson, to receive a neurologic evaluation in order to assess the developmental difficulties mentioned previously. In his decision dismissing the case, Special Master Corcoran noted that at this evaluation J.J.N.'s mother "made no mention of the vaccinations J.J.N. had received in September or November as having any relationship in her understanding to his symptoms, although she did mention the early October tick bite." Id. The nurse practitioner at the neurologic examination referenced "two episodes of altered consciousness" in J.J.N.'s history, one occurring in early October of 2014 when he "had increased irritability" and "was lethargic." The nurse practitioner took note of this episode as a "possible seizure." The second noted episode occurred on November 8, 2014, when J.J.N. was found "on the floor face down with his head to the side" and "limp" after jumping on a trampoline. According to medical records submitted by petitioners, J.J.N. was "somewhat tired" throughout the next day after the November 8, 2014 episode. During the neurologic evaluation on December 11, 2014, the nurse practitioner noted, "[w]e are also suspicious that this is leading to a possible Autism diagnosis and we will carefully monitor him over the next few months." An MRI performed on January 29, 2015, revealed

J.J.N. has a "highly unusual configuration of the corpus callosum," but there was "[n]o conclusive evidence for an underlying metabolic condition." On March 4, 2015, at a follow-up neurological evaluation, a nurse practitioner deemed J.J.N.'s "global regression" of his development "strongly suggestive" of "traits of an autism spectrum disorder." The nurse practitioner recommended speech and physical therapy for J.J.N., and noted that his "Fragile X testing" was negative. Special Master Corcoran stated that the medical record provided by petitioners after the March 4, 2015 follow-up neurological examination "discloses Petitioners' consistent efforts to provide J.J.N. the care necessary to treat his developmental problems, but largely do not impact analysis of the present claim, and therefore are not further discussed." See K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *3.

On October 3, 2017, petitioners filed their <u>pro</u> <u>se</u> petition on behalf of J.J.N. for compensation under the National Vaccine Injury Compensation Program pursuant to the Vaccine Act. Petitioners allege that "[p]rior to the administration of his September 24 2014 vaccination petitioner was in good health and suffered no medical conditions." Petitioners also allege that on November 5, 2014, J.J.N. experienced various non-Table⁷ injuries, including "Fever and Behavioral change." (capitalization in original). It is also alleged that

[S]uffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

⁵ The "corpus callosum" is defined as "an arched mass of white matter, found in the depths of the longitudinal fissure, composed of three layers of fibers, the central layer consisting primarily of transverse fibers connecting the cerebral hemispheres." <u>Dorland's Illustrated Medical Dictionary</u>, 417 (32nd ed. 2012).

⁶ Fragile X syndrome is defined as "an X-linked syndrome associated with a fragile site on the X chromosome . . . associated with mental retardation . . . in most males and mild mental retardation in many heterozygous females." <u>Dorland's Illustrated Medical Dictionary</u>, 1830.

⁷ For Vaccine Program claims, a petitioner may allege a Table injury or a non-Table injury. <u>See generally</u> 42 C.F.R. § 300aa-11(c) (2018). A Table injury is defined as a claim that demonstrates "that the person who suffered such injury or who died," was the recipient of "a vaccine set forth in the Vaccine Injury Table," and that the recipient "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine." <u>See</u> 42 C.F.R. §§ 300aa-11(c)(1)(A), 300aa-11(c)(1)(C)(i). A non-Table injury is defined as a claim that is not included on the Vaccine Injury Table and that demonstrates that a recipient of a vaccination:

on "Nov 14 2014," J.J.N. "presented to Dr. Wilson after experiencing Seizure activitey [sic], unresponsive episodes and mental status change." On February 14, 2018, petitioners filed an amended petition. The only Table claim that petitioners allege in the amended petition is that of an "acute encephalopathy," which is a Table claim for the MMR and DTaP vaccinations. Petitioners allege that J.J.N. experienced symptoms of an acute encephalopathy after his November 25, 2014 vaccinations.

Petitioners also describe other non-Table claims of "adverse effects" to vaccinations J.J.N. had received on September 24, 2014, which petitioners describe as follows:

After receiving these vaccinations, the petitioner developed diarrhea, drowsiness, lethargy, severe irritability, fever, tremors, loss of appetite, symptoms of severe pain including high pitched scream and "writhing" in pain alteration in mental status loss of consciousness behavioral changes, vomiting, and seizure. Petitioner also requests compensation for injury consistent with acute encephalopathy resulting from adverse effect of a set of vaccines received on November 25, 2014 including MMR #1, Varicella #1, Fluzone Quad State, and DTAP #5 After which he developed symptoms of acute encephalopathy. These symptoms included period of lethargy, severe irritability, behavioral changes he became inconsolable, and incredibly difficult to comfort or soothe, screaming and crying, he developed expressive aphasia.[9] [J.J.N.] experienced negative side effects after a hepatitis A vaccine January 6, 2018.

[F]ocal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy.

⁸ An encephalopathy is defined as "any degenerative disease of the brain." <u>Dorland's</u> Illustrated Medical Dictionary, 614. The Vaccine Act explains that common symptoms are:

⁴² U.S.C. § 300aa-14(b)(3)(A). An acute encephalopathy can be a Table injury for the DTaP and MMR vaccines, and is indicated by "a significantly decreased level of consciousness that lasts at least 24 hours," occurring within 72 hours after vaccination (DTaP) or within five to fifteen days after vaccination (MMR). See 42 C.F.R. § 100.3(c)(2)(i)(A)(1) (2018).

⁹ Expressive aphasia is a defect or loss of motor skills. <u>Dorland's Illustrated Medical</u> Dictionary, 115.

(capitalization and grammar in original). Petitioners assert they did not "seek emergency treatment" for J.J.N.'s "symptoms of acute encephalopathy" as they were previously reassured by medical practitioners that this lethargy was "normal" after routine vaccinations. In their petition for compensation, petitioners state that J.J.N.'s "physical and developmental assessments" at his November 25, 2014 checkup were "within normal limits according to the petitioners age."¹⁰

During the time this case was assigned to Special Master Thomas L. Gowen, he ordered petitioners to file all relevant medical records and a statement of completion¹¹ by November 28, 2017.¹² Special Master Gowen held a status conference with both parties on March 27, 2018. On May 30, 2018, the Chief Special Master, pursuant to Vaccine Rule 3(d), reassigned the case to Special Master Brian H. Corcoran. As the original statutory period for a decision had expired, ¹³ Special Master Corcoran allowed petitioners to submit a notice of intent to remain in the Program, which petitioners did on June 29, 2018. Thereafter, Special Master Corcoran held a status conference with both parties on July 12, 2018.

After the status conference, on July 16, 2018, Special Master Corcoran ordered respondent to file a "Rule 4(c) Report[14] on or before August 31, 2018. Respondent should also file a Motion to Dismiss (along with the report) if he [sic] deems appropriate in light of the medical record evidence." See Order at 3, K.N. v. Sec'y of Health & Human Servs., No. 17-1418V (Fed. Cl. Spec. Mstr. July 16, 2018). Also, in his July 16, 2018 Order, Special Master Corcoran advised J.J.N.'s mother to "continue to supplement the record with additional medical records (e.g., proof of vaccination, birth records and medical records prior to the vaccination, as well as records post-vaccination relating to

¹⁰ In the record before this court, that same checkup on November 25, 2014, noted a "[c]all into Neurology and appts pending with Neuro and Developmental Peds."

¹¹ A statement of completion is a statement by a petitioner, filed with the court, that signifies "that petitioner believed that all relevant medical records had been filed." <u>Dhanoa v. Sec'y of Health & Human Servs.</u>, No. 15–1011V, 2017 WL 6276468, at *1.

¹² After several motions for extension of time, petitioners filed an amended petition and some exhibits on February 14, 2018. A further motion for an extension of time was granted by Special Master Gowen, giving petitioners until July 27, 2018 to file all records and the statement of competition. A statement of completion, however, never was filed by petitioners with the Office of Special Masters.

¹³ The decision of the Special Master must "be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed." 42 U.S.C. § 300aa-12(d)(3)(A)(ii).

¹⁴ The respondent, "[w]ithin 90 days after the filing of a petition, or in accordance with any schedule set by the special master after petitioner has satisfied all required documentary submissions," must file a report with a statement as to "why an award should or should not be granted." Vaccine Rule 4(c)(1) (2018).

the injury and any relevant affidavits) in order to better support her claim." <u>See id.</u> at 2. In addition, in his July 16, 2018 Order, Special Master Corcoran indicated that since the Omnibus Autism Proceedings, ¹⁵ "no petitioners asserting non-Table causation claims alleging that a child developed autism (or experienced an autistic-like developmental regression) after receipt of a vaccine have succeeded in obtaining favorable entitlement decisions." <u>See id.</u> at 1 (emphasis in original).

Respondent filed a Vaccine Rule 4(c) Report and a motion to dismiss for "failure of proof" on August 31, 2018. In the Vaccine Rule 4(c) Report, respondent asserted that medical personnel of the Division of Injury Compensation Programs at the Department of Health and Human Services asserted that petitioners' case was not "appropriate for compensation under the terms of the Vaccine Act." In the motion to dismiss, respondent argued "J.J.N.'s records do not provide the requisite evidence to meet petitioners' burden of proof and petitioners have not provided a reputable medical or scientific theory showing that J.J.N.'s vaccinations caused any of J.J.N.'s various alleged symptoms." Respondent stated that "a majority of the symptoms alleged in the Petition" are "commonly seen in children with ASDs [Autism Spectrum Disorders]." Respondent also noted that this court has "consistently rejected other petitioners' characterizations of ASDs as an encephalopathy or some other injury in an attempt to circumvent the binding effect of the OAP [Omnibus Autism Proceedings] decisions." Furthermore, according to respondent, "even if" some of the symptoms were distinct from J.J.N.'s Autism Spectrum Disorder. "several of" them began before the beginning of the Act's "three-year limitations period" and many do not satisfy the "six-month requirement" 16 because "they were transient in nature."

Despite Special Master Corcoran's guidance in his Rule 4 Order regarding the need to supplement the record in order to support their petition, petitioners made no substantive filings in the almost seven months between the status conference and the

See Order at 2 n.1, K.N. v. Sec'y of Health and Human Servs., No. 17-1418V.

¹⁵ Special Master Corcoran's July 16, 2018 Order contains a detailed footnote which describes the Omnibus Autism Proceedings. He indicated that in the Omnibus Autism Proceedings, after trying multiple cases, and issuance of:

[[]A] total of eleven lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit, unanimously rejected petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism.

¹⁶ Pursuant to 42 U.S.C. § 300aa-11(c)(1)(D)(i), for either a Table claim or a non-Table claim, a petition shall contain "supporting documentation[] demonstrating" that the petitioners "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i) (punctuation omitted).

February 4, 2019 dismissal of the case by Special Master Corcoran. The only filing petitioners made was a statement opposing respondent's motion to dismiss, filed almost four months after the motion to dismiss was filed and after the deadline set by the Special Master. 17 The Special Master, however, did accept petitioners' late filing. In their opposition to the motion to dismiss, petitioners asserted that dismissal would be inappropriate because J.J.N. "requires further medical testing to determine the actual scientific reason for his multiple inappropriate responses to routine vaccinations." Petitioners assert that J.J.N.'s eczema is "relevant because it indicates that clearly [J.J.N.] doesn't react appropriately to Dtap [sic]." Petitioners also raised a new allegation that J.J.N. may have a "mitochondrial or metabolic disorder," and indicated that a diagnosis was "pending." In reference to J.J.N.'s alleged symptoms of an acute encephalopathy, J.J.N.'s mother stated that she "believed this lethargy was normal under these circumstances. As such I did not report his lethargy to anyone, nor did I seek appropriate care for that lethargy." In his decision dismissing the case, Special Master Corcoran notes that petitioners' opposition to the motion to dismiss largely recited factual allegations that were not based on evidence in the record and that petitioners had provided no additional evidence to support their claim. See K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *3.

In his February 4, 2019 dismissal, Special Master Corcoran found the evidence submitted by the petitioners to "not establish the Table requirements for encephalopathy," with regards to J.J.N.'s claim. See id. at *4. With regards to petitioners' Table claim of an acute encephalopathy, Special Master Corcoran found petitioners' argument that the "alarming degree of [J.J.N.'s] symptoms" and the alleged "3 days of acute lethargy" were undocumented in the medical record because of "error" to be "not enough for a successful Program claim." Id. at *3-4. Special Master Corcoran found "no evidence" that J.J.N. had "experienced an acute (meaning sufficient to require hospitalization) or subsequent chronic encephalopathy after his September or November 2014 vaccinations." Id. at *4. Rather, Special Master Corcoran found the most compelling evidence of altered consciousness to be J.J.N.'s possible seizure in the beginning of October 2014, and incident falling off of the trampoline on November 8, 2014 that were both discussed at J.J.N.'s December 11, 2014 neurologic evaluation. See id. These instances, as the Special Master notes, "preceded the November vaccinations." See id. (emphasis in original). Special Master Corcoran took specific note that with regards to their Table claim of acute encephalopathy, petitioners "did not file any such additional evidence, despite

¹⁷ Petitioners filed two motions for an extension of time. Each time, petitioners requested an extension of ninety days. Special Master Corcoran granted in part and denied in part both motions, giving petitioners thirty-five days for their first motion and twenty-one days for their second motion, setting a filing due date of December 21, 2018 after petitioners' second motion for an extension of time. In his order granting in part and denying in part petitioners' first motion for an extension of time, Special Master Corcoran noted he believed petitioners' request for an extension of "ninety days would cause undue delay in the resolution of this matter and is therefore excessive." With regards to petitioners' second motion for an extension of time, Special Master Corcoran indicated that he felt the lengthy extension petitioners requested was "not reasonable or called for."

having had more than three months to act since the filing of Respondent's motion to dismiss." See id.

Regarding petitioners' various alleged non-Table claims, the Special Master found the record "similarly unsupportive" of petitioners' claims. See id. Special Master Corcoran found petitioners' assertion that J.J.N.'s eczema was proof of "a propensity for an autoimmune response (which presumably occurred again after the November 2014 vaccinations) is also unsupported by the record." 18 Id. at *4 n.7. The "temporal association" of J.J.N.'s symptoms and vaccinations, according to the Special Master, is "not enough for a successful Program claim." See id. at *4. Special Master Corcoran also indicated that "it appeared that the Petitioners wished to argue that J.J.N.'s autism was vaccine-caused." Id. at *1. In his decision the Special Master stated, however, that "attempting to characterize developmental symptoms as the secondary result of a vaccine-induced encephalopathy" in a Program claim "had uniformly failed." Id. at *5. The Special Master noted that in order to receive compensation under the Vaccine Program, petitioners needed to prove that:

[E]ither (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of J.J.N.'s vaccinations (in which case establishing causation-in-fact is not required), or (2) that J.J.N. suffered an injury that was actually caused by a vaccine. See Sections 13(a)(1)(A) and 11(c)(1). Petitioners seeking to establish entitlement via a causation-in-fact must meet the three-prong test for such a claim set forth by the [United States Court of Appeals for the] Federal Circuit in Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005).

See K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *4 (italics and parentheses in original) (citing 42 U.S.C. §§ 300aa-13(a)(1)(A) and 11(c)(1)). The Special Master found that the petitioners had not "successfully distinguished this case from the many autism claims that have been litigated unsuccessfully in the Program." Id. at *5.

The Special Master also stated that "Petitioners' desire to vary what the existing records establish with their own recollections fly in the face of long-standing Program law holding that contemporaneous records are deemed accurate except in limited circumstances not established to be relevant here." <u>Id.</u> at *4 (citing <u>Burns v. Sec'y of Health & Human Servs.</u>, 3 F.3d 415, 417 (Fed. Cir. 1993)). Because the petition was not

¹⁸ The Special Master noted that J.J.N. was assessed by an allergist, "and the assessment was atopic dermatitis, allergic rhinitis, and recurrent bacterial infection. . . . No treater, however, linked any of the above to the DTaP vaccine or deemed it out of the ordinary." K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *4 n.7 (citation omitted).

"supported by either medical records or by the opinion of a competent physician," Special Master Corcoran found that petitioners' claim "must be dismissed." 19 Id. at *5.

On February 13, 2019, after their claim was dismissed by Special Master Corcoran, petitioners filed a "Notice of Appeal" improperly titled as an appeal to the United States Court of Appeals for the Federal Circuit. Petitioners should have filed a motion for review in the United States Court of Federal Claims. See Vaccine Rule 23. On February 22, 2019, Special Master Corcoran issued a Deficiency Order directing petitioners to file a proper "motion for review" with this court. In the Deficiency Order, Special Master Corcoran informed the petitioners they had to seek review by March 7, 2019, although the statutory deadline was March 6, 2019. Based on the Special Master's direction, petitioners filed their motion for review and memorandum of objection in this court on March 7, 2019. Following remand to the Special Master, Special Master Corcoran issued an Order on March 15, 2019, which stated, "[p]etitioners' initial filing could reasonably be deemed to have satisfied the temporal requirements for motions for review under the [Vaccine] Act and the Vaccine Rules." Order on Remand at 3, K.N. v. Sec'y of Health & Human Servs., No. 17-1418V (Fed. Cl. Spec. Mstr. March 15, 2019). Acknowledging petitioners' pro se status and his own calculation error, the Special Master stated that it was "proper to deem Petitioners' February 13, 2019 submission to the clerk's office as a timely motion for review of my February 4th Decision with the Court of Federal Claims." ld. The petition now comes to this court on petitioners' motion.

In this court, petitioners "respectfully request that the court Reconsider this petition, and supporting proof." Petitioners now also allege that since the dismissal of their claim they have made discoveries that "support [the] petition" and are "awaiting a genetic diagnosis." In their memorandum of objection, filed with their motion for review,

¹⁹ With regards to petitioners' claim in their amended petition that J.J.N. experienced an alleged reaction to a hepatitis A vaccine, the Special Master noted that "Petitioners' Opposition makes no mention of their prior assertion that J.J.N. experienced some kind of reaction after receiving the Hep A vaccine in January 2018, and I similarly find that the record is not supportive of a Vaccine Program award based upon such allegations." K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *4 n.6.

²⁰ Along with their motion for review petitioners submitted over 350 new pages of medical records, therapy reports, and school evaluations for J.J.N. to this court, which had not been submitted to Special Master Corcoran prior to his dismissal of petitioners' claim. Because the new evidence never was submitted to Special Master Corcoran, it is not properly before this court on review of the Special Master's decision, and, therefore, is not part of the record for the court's current review. Vaccine Rule 8 guides submission of evidence, and Vaccine Rule 8(f)(1) specifically states that "[a]ny fact or argument not raised specifically in the record before the special master will be considered waived and cannot be raised by either party in proceedings on review of a special master's decision." Vaccine Rule 8(f)(1) (2018). Even a brief review of petitioners' attempted filing of supplemental records, however, does not appear to provide evidence to prove that J.J.N. suffered an acute encephalopathy or developmental regression from his vaccinations.

petitioners try to assert a new argument that was not before the Special Master, and allege that J.J.N.'s reaction to the vaccines occurred because "he most probably has a mitochondrial disorder caused by an X linked genetic disorder which both the petitioners and his healthcare providers were unaware of at the time both sets of 'catch up' vaccines were administered on sept 24 and Nov 25 of 2014." Petitioners assert this disorder is proven by signs of "[m]etabolic dysfunction" and that "[t]his genetic disorder is thought to be incredibly rare, due to particularly rare abnormality of [J.J.N.'s] corpus callosum," but note that "specific diagnosis is pending." In their memorandum of objection, filed with the motion for review with this court, petitioners now allege that "a mitochondrial disorder that we were unaware of caused an immune stimulation that required more metabolic energy then available," which, "after his September 24, 2014 immunizations," caused J.J.N. to have "developed significant neurological symptoms over the period of several weeks." This "mitochondrial disorder" is alleged by petitioners to have "manifested in regressive encephalopathy with features of autism spectrum disorder."

The new submission is speculative, unconnected, and largely not relevant to the allegations raised by petitioners before Special Master Corcoran, and now under review by this court. Therefore, even if the additional evidence petitioners tried to submit to this court was properly before this court, which it is not, or had been before the Special Master, the newly submitted evidence would not appear to change the determination in this case.

²¹ As indicated above, with their filing in this court, together with petitioners' memorandum of objection, petitioners submitted, and tried to rely on, additional documents, including an affidavit and examination records apparently authored by Dr. Andrew Zimmerman, which were not submitted to the Special Master before he issued his decision and, which therefore, are not properly before this court. Petitioners allege Dr. Zimmerman cared for J.J.N. for "a short period of time." Petitioners attempted to file selected pages of records from a one hour examination of J.J.N. by Dr. Zimmerman on May 17, 2018, forty minutes of which are described as counseling, and also attempted to file pages from a brief thirty minute follow-up examination of J.J.N., on July 10, 2018, of which twenty minutes are described as counseling.

Based on Dr. Zimmerman's affidavit, petitioners argue that "there were exceptions in which vaccinations could cause autism," and that the reason the vaccinations caused J.J.N.'s autism is "a genetic abnormality." The court notes, however, that the patient in the affidavit to which Dr. Zimmerman refers is a patient other than J.J.N., and appears to have been submitted in an unrelated case. Petitioners assert that at the May 17, 2018 visit with Dr. Zimmerman, they mentioned obtaining lab testing of "metabolic functions," and that they raised their concern about J.J.N.'s reaction to the "DTaP" vaccines, as well as "any other underlying disease causing [J.J.N.'s] ASD [Autism Spectrum Disorder]." The court notes that at the July 10, 2018 follow-up examination there was no mention of anything conclusive other than that J.J.N.'s "metabolic profile" was "normal."

Moreover, as the respondent asserts, Dr. Zimmerman stated in his affidavit that his "opinions as to vaccine causation were case-specific," and that Dr. Zimmerman "evaluated J.J.N." and that Dr. Zimmerman "did not attribute J.J.N.'s ASD to vaccines."

On April 5, 2019, respondent filed a response to petitioners' motion for review in this court. In the response, respondent requests this court affirm the decision of Special Master Corcoran because the Special Master "correctly concluded" that the record did not prove J.J.N. suffered a Table injury of acute encephalopathy. With regards to petitioners' various non-Table claims, respondent argues that Special Master Corcoran "correctly concluded that the record does not support a claim that J.J.N. suffered a reaction to his September and/or November 2014 vaccinations that explains his neurological symptoms." Respondent also argues that petitioners have not established that their claim is more than a "temporal association," and requests that this court affirm the Special Master's decision because "Petitioners have failed to demonstrate that the Special Master erred, or that his actions were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." Remarking that petitioners did not file an expert report while the Special Master was considering the case, respondent also argues that petitioners' new filings submitted with their motion for review are "not properly before this Court" according to Vaccine Rule 8.

DISCUSSION

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

In order to recover under the Vaccine Act, a petitioner "must show, by a preponderance of the evidence, "that the injury or death at issue was caused by a vaccine." Milik v. Sec'y of Health & Human Servs., 822 F.3d 1367, 1379 (Fed. Cir. 2016); (quoting Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1341 (Fed. Cir. 2010) (citing 42 U.S.C. §§ 300aa–11(c)(1), –13(a)(1)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355-56 (Fed. Cir. 2013) ("The Vaccine Act created the National Vaccine Injury Compensation Program, which allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had significantly aggravated' a vaccine-related 'illness, disability, injury, or

condition." (quoting 42 U.S.C. § 300aa–11(c)(1)(C))); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1350 (Fed. Cir. 2011) ("A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine."); see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013); Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011).

As the United States Court of Appeals for the Federal Circuit explained:

A petitioner can establish causation in one of two ways. <u>Id.</u> [Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1341] If the petitioner shows that he or she received a vaccination listed on the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed on that table within a statutorily prescribed time period, then the Act presumes the vaccination caused the injury. <u>Andreu v. Sec'y of Health & Human Servs.</u>, 569 F.3d 1367, 1374 (Fed. Cir. 2009). Where, as here, the injury is not on the Vaccine Injury Table, the petitioner may seek compensation by proving causation-in-fact.

Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379 (citing Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1374); see also Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992). The Federal Circuit has held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2008) (quoting the Restatement (Second) of Torts § 431(a)); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1367 (Fed. Cir.) reh'g and reh'g en banc denied (Fed. Cir. 2013) ("To prove causation, a petitioner must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury." (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352–53)). A "'substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." Id. (citing Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)).

Under the off-Table theory of recovery, a petitioner is entitled to compensation if he or she can demonstrate, by a preponderance of the evidence, see 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table, but which was caused by a vaccine that is listed on the Vaccine Injury Table. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356

("Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322)); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines on Behalf of Sevier v. Sec'y of Health & Human Servs., 940 F.2d at 1525. While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly ex rel. v. Sec'y of Health & Human Servs., 592 F.3d at 1324; see also Hazlehurst v. Sec'y of Health & Human Servs., 88 Fed. Cl. 473, 479 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010) (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009)).

According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80 (citing concurrence in judgment in Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("In this off-table case, the petitioner must show that it is 'more probable than not' that the vaccine caused the injury." (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80)). A petitioner who meets this burden is then entitled to recovery under the Vaccine Act, unless the respondent proves by preponderant evidence that the injury was caused by factors unrelated to the vaccine. See Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. 672, 680 (2016) (citing 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995)); Walther v. Sec'y of Health & Human Servs., 485 F.3d at 1151. "But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case." Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680 (citing Stone v. Sec'y of Health & Human Servs., 676 F.3d at 1379; de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1353).

In Markovich v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366 (The United States Court of Appeals for the Federal Circuit stated that "we 'perform[] the same task as the Court of Federal Claims and determine[] anew whether the special master's findings were arbitrary or capricious." (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))) (brackets in original); W.C. v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under the

same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh'g and reh'g en banc denied (Fed. Cir. 2008); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1350; Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 817 (2013). The arbitrary and capricious standard is "well understood to be the most deferential possible." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992).

This court may set aside a Special Master's decision only if the court determines that the "findings of fact or conclusion of law of the special master . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" 42 U.S.C. § 300aa-12(e)(2)(B); see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1350 ("We uphold the special master's findings of fact unless they are arbitrary or capricious.") (internal citations omitted); Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Markovich v. Sec'y of Health & Human Servs., 477 F.3d at 1356-57; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360. The United States Court of Appeals for the Federal Circuit has indicated that:

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard. . . ; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Health & Human Servs., 970 F.2d at 871 n.10; see also Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Griglock v. Sec'y of Health & Human Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010)) (explaining that the reviewing court "doles] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder") rehig and reh'g en banc denied (Fed. Cir. 2012); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56, "[T]he special masters have broad discretion to weigh evidence and make factual determinations." Dougherty v. Sec'y of Health & Human Servs., 141 Fed. Cl. 223, 229 (2018). "With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference - no change may be made absent first a determination that the special master was 'arbitrary and capricious." Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B).

Generally, "if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines on Behalf of Sevier v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Human Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Health & Human Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a "rational connection between the facts found and the choice made." (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

As noted by the United States Court of Appeals for the Federal Circuit:

Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366-67 (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)) (modification in original); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363; Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012). The Court of Appeals for the Federal Circuit further has explained that the reviewing courts "do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious." See Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 (quoting Lampe v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

The Special Master has discretion to determine the relative weight of evidence presented, including contemporaneous medical records and oral testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d at 417 (finding that the Special Master had thoroughly considered evidence in record, had discretion not to hold an additional evidentiary hearing); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1368

(finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict). "Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Dept. of Health & Human Servs., 970 F.2d at 870 n.10); see also Rich v. Sec'y of Health & Human Servs., 129 Fed. Cl. 642, 655 (2016); Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 467 (2012) ("So long as those findings are 'based on evidence in the record that [is] not wholly implausible,' they will be accepted by the court." (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363 (alteration in original))). "Determinations subject to review for abuse of discretion must be sustained unless 'manifestly erroneous." Heddens v. Sec'y of Health & Human Servs., 143 Fed. Cl. 193, 197 (2019) (citing Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 53 (2005) (citations omitted)).

Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 728 (2009); see also Paluck ex rel. Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Human Servs., 601 F.3d at 1355], he cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2011))).

With regard to the Special Master's weighing of evidence when testimony conflicts with contemporaneous medical records, the Special Master generally should afford contemporaneous medical records greater weight than conflicting testimony offered after the fact. Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed Cir.) (citing United States v. United States Gypsum Co., 333 U.S. 364, 396 (1947) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")) reh'g denied (Fed. Cir. 1992). This is because medical records created contemporaneously with the events they describe are presumed to be accurate and complete. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

In the case now before this court, the evidence in the record demonstrates that Special Master Corcoran reviewed the record before him, and even tried to help the <u>prose</u> petitioners understand the process of proving a vaccine case and what kind of evidence would be required to prove causation. Once assigned to the case, Special Master Corcoran held a status conference regarding petitioners' allegations. Following "an initial review of the claim and documents offered in its support," the Special Master "explained to Petitioners' that the claim faced considerable obstacles," to prove causation, but he would afford petitioners an "opportunity to file whatever medical records they proposed could establish this had occurred." See K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *1. Following the Special Master's July 16, 2018 Order, however,

petitioners filed no additional medical records or an expert report with Special Master Corcoran.

In his decision dismissing the case for insufficient proof, the Special Master fully explained why, based on the record before him, he found the record to be insufficient to establish petitioners' Table claim of acute encephalopathy or petitioners' various non-Table claims. Special Master Corcoran stated:

Petitioners' desire to vary what the existing records establish with their own recollections fly in the face of long-standing Program law holding that contemporaneous records are deemed accurate except in limited circumstances not established to be relevant here . . . And in any event, Petitioners did not file any such additional evidence, despite having had more than three months to act since the filing of Respondent's motion to dismiss.

Id. at *4 (citation omitted).

Regarding petitioners' Table claim of acute encephalopathy, Special Master Corcoran explained in his dismissal that petitioners' allegations required proof of "a significantly decreased level of consciousness that lasts at least 24 hours" occurring within 72 hours after vaccination [DTaP] or within five to fifteen days after vaccination [MMR] to constitute a valid Table claim for either the DTaP or the MMR vaccines. See 42 C.F.R. § 100.3(c)(2)(i)(A)(1). According to petitioners' exhibits, J.J.N. did not receive the DTaP or MMR vaccinations at the September 24, 2014 physical examination and so the only time period in question with regards to petitioners' Table claim for an alleged acute encephalopathy only could have been following the November 25, 2014 vaccinations. Special Master Corcoran did not find petitioners to have established their allegation that J.J.N. suffered a Table claim of an acute encephalopathy because contemporaneous medical record establishes no evidence" of J.J.N.'s symptoms at the relevant time. See K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *4. The Special Master indicated that "J.J.N.'s instances of altered consciousness preceded the November vaccinations, further harming the argument that that date was the start of a Table encephalopathy, and the most alarming medical occurrence after the September vaccinations was the October tick bite." Id. (emphasis in original). The court agrees with the Special Master's conclusion that the medical record does not support a claim of J.J.N. experiencing an acute encephalopathy following his November 25, 2014 vaccinations.

Special Master Corcoran also found in his dismissal that the record is "similarly unsupportive" of petitioners' various non-Table claims that, according to the petitioners, J.J.N. experienced "a reaction to his September and November 2014 vaccinations—whether separately or together culminating in the ASD [Autism Spectrum Disorder] symptoms he has experienced." See id. (footnote omitted). Special Master Corcoran wrote in his dismissal that "Petitioners have not successfully distinguished this case from the many autism claims that have been litigated unsuccessfully in the Program." Id. at *5. The Special Master also pointed out that "non-Table claims alleging a vaccine-caused"

developmental problem (whether or not the petitioners agreed it was autism) decided since the conclusion of the OAP [Omnibus Autism Proceedings] had uniformly failed." Id. (citing Thompson v. Sec'y of Health & Human Servs., 2017 WL 2926614, at *13 (Fed. Cl. Spec. Mstr. May 16, 2017) (citing Wolf v. Sec'y of Health & Human Servs., No. 14-342V, 2016 WL 651858, at *15 (Fed. Cl. Spec. Mstr. Sept. 15, 2016))).

With regards to petitioners' claim that J.J.N.'s alleged eczema was proof that he "doesn't react appropriately to Dtap [sic]," Special Master Corcoran correctly noted that "Petitioners' assertions that J.J.N. displayed a sensitivity to the DTaP vaccine, revealed in the winter of 2014 after receiving initial doses of it, and that this sensitivity reflects a propensity for an autoimmune response (which presumably occurred again after the November 2014 vaccinations) is also unsupported by the record." K.N. v. Sec'y of Health & Human Servs., 2019 WL 1123016, at *4 n.7.

Petitioners, in their motion for review in this court, now allege a new theory which was not before the Special Master and, therefore, is not properly before this court, but which petitioners have apparently developed since the deadlines for submitting proof to the Special Master and when the Special Master dismissed their case. Petitioners now argue that this theory proves that J.J.N.'s vaccinations "'significantly aggravated an underlying metabolic disorder, which predisposed her' (in this situation JJN) 'to deficits in cellular energy metabolism' . . . 'and manifested in regressive encephalopathy with features of autism spectrum disorder." Petitioners assert that J.J.N. "most probably has a mitochondrial disorder caused by an X linked genetic disorder which both the petitioners and his healthcare providers were unaware of at the time both sets of 'catch up' vaccines were administered on sept 24 and Nov 25 of 2014." There is no medical evidence in the record that J.J.N. actually has a metabolic disorder or experienced a regressive developmental encephalopathy. Even if petitioners' attempted new filings were properly before this court, which, as discussed above, they are not, those filings are unsupportive of petitioners' claim. Even the testing of J.J.N. for an X-linked disorder, which petitioners assert is the cause of the "mitochondrial disorder," was negative. Moreover, the only primary care provider to assess J.J.N. with a metabolic disorder never addressed the cause of the dysfunction in J.J.N., nor the symptoms he may have experienced as a result.

The record before the court supports the Special Master's decision to dismiss petitioners' case for insufficient proof and demonstrates that Special Master Corcoran rationally concluded that petitioners' exhibits and personal recollections do not overcome the presumption in favor of the information contained in the contemporaneous medical record. See Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d at 1369; see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870. As indicated above, with exceptions that petitioners have not proven here, the existing case law consistently has found contemporaneous medical records to be weighed more than oral testimony after the fact. Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. at 733 (citing United States v. United States Gypsum Co., 333 U.S. at 396 ("It has generally been held that oral

testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

Petitioners have provided no reputable medical or scientific explanation to support the claims alleged in their petition. See Grant v. Sec'y of Health & Human Servs., 956 F.2d at 1148 (The Federal Circuit determined a "reputable medical or scientific explanation" to be "evidence in the form of scientific studies or expert medical testimony."). As petitioners have presented no evidence to establish vaccine induced causation, and because "[t]he special master or court may not make such a finding based on the claims of a petitioner alone," the Special Master's decision was not arbitrary, capricious, an abuse of discretion or contrary to law. See 42 U.S.C. § 300aa-13(a)(1). This court, therefore, affirms Special Master Corcoran's February 4, 2019 dismissal of petitioners' claims. While this court sympathizes with petitioners regarding any medical difficulties J.J.N. may have experienced, or is continuing to experience, petitioners have not offered sufficient proof that J.J.N.'s alleged encephalopathy or other alleged symptoms, including "features of autism spectrum disorder," were caused by the vaccinations he received.

CONCLUSION

As determined above, upon review of the evidence admitted into the record before the Special Master, the court **AFFIRMS** Special Master Corcoran's finding of insufficient evidence to meet petitioners' burden of proof and the Special Master's denial of petitioners' claim for compensation on behalf of J.J.N.

IT IS SO ORDERED.

MARIAN BLANK HORN Judge